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Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

2014 Meeting
Geneva, 1-5 December 2014

Biological Weapons Convention
Meeting of Experts
Geneva, 4-8 August 2014
Item 5 of the agenda
Standing agenda item: cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X

Report on USA implementation of Article X of the Biological and Toxin Weapons Convention

Submitted by the United States of America

Article X

(1) The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes.

(2) This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

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I. Background

1. The United States is firmly committed to fulfilling all of its obligations under the Biological and Toxin Weapons Convention (BWC), including those under Article X of the Convention. Activities relevant to implementation of Article X include – but are by no means limited to – assistance programmes, and encompass a wide range of activities in support of the overall advancement and application of the life sciences for peaceful purposes. The Seventh Review Conference rightly recognized this, and in addition to establishing an Assistance and Cooperation Database, requested States Parties to report on their implementation, in order to produce a more complete picture of Article X implementation.

2. Article X embodies an international commitment to partnership, sharing of information, networking, and the development of mutually beneficial outcomes. While the United States has supported, and will continue to support, capacity building and other forms of assistance for those countries seeking it, formal "assistance" programmes comprise only a part of this much larger undertaking. Through our broad-ranging efforts, the United States and the international community have worked together collectively to pursue shared goals, including, *inter alia*:

- Improving global health security by preventing, detecting, and responding effectively to disease;
- Advancing educational and collaborative opportunities for the international scientific community;
- Contributing to the advancement of biological sciences for peaceful purposes;
- Creating an international system that promotes innovation, investment, and access to scientific advances to address environmental, health, energy, and other needs; and
- Building sound, appropriate regulatory and oversight systems at all levels to ensure the safe and peaceful application of dual-use materials and technologies, and the effective implementation of BWC and United Nations Security Council Resolution (UNSCR) 1540 obligations.

3. We continue to invest significant resources in these efforts. In the United States system, exchange, cooperation, and assistance in fulfillment of our Article X commitments are provided in a variety of ways: bilaterally by the United States. Government to other national entities; through national contributions to international organizations; and by individuals, industry, foundations, and academia, all of which are critical players in American civil society. This multidimensional approach is reflected in this report, which is organized around the three basic commitments contained in Article X: (1) to facilitate the fullest possible exchange of information, equipment, and materials for peaceful purposes; (2) to contribute to the advancement and application of the life sciences; and (3) to implement the BWC in ways that avoid hampering the economic and technological development of States Parties.

4. We believe that the exchanges during the BWC intersessional process have been productive in building relationships and facilitating real assistance on issues of practical concern to States Parties. However, as previous Review Conferences have noted, while the large number of U.S. programs and wide range of ongoing efforts underway contribute to our implementation of Article X, such efforts do not take place solely, or even primarily, in the BWC forum. The United States will continue to utilize this broad diversity of institutions, stakeholders, and fora in order to pursue our shared goals for international cooperation and assistance.

5. The breadth and scope of U.S. contributions and assistance precludes a comprehensive listing of each and every program in its entirety, but enclosed in this paper is a selection of examples that illustrate the range of our activity and amply document our full commitment to the letter and spirit of Article X, including links to a variety of online resources. We have also included a specific example of a request for assistance and a U.S. response facilitated through the Assistance and Cooperation Database. Additionally, the United States provides one-page descriptions of some of our assistance programmes at each Meeting of Experts and Meeting of States Parties, along with contact information. These one-page descriptions are also submitted to the BWC Implementation Support Unit, and included in the Assistance and Cooperation Database established by the 2011 Review Conference.

II. Bilateral, regional, and multilateral efforts to facilitate the fullest possible exchange of biological equipment, materials, and information for peaceful purposes

6. The United States engages actively through bilateral, regional, and multilateral channels, and through these substantial interactions works to facilitate the exchange of biological equipment, materials, and information and the application of scientific advances for peaceful purposes. The United States Government, in particular, provides support that enables scientists to participate in and foster the exchange of ideas that advances our mutual understandings in the life sciences.

7. The United States is one of the largest economies in the world and the largest exporter and importer of goods and services, with U.S. exports hitting a record of $2.3 trillion in 2013. In 2010, the United States launched the National Export Initiative (NEI), which has sought to improve conditions that directly affect the private sector's ability to export. The NEI works to remove trade barriers abroad, by helping firms (especially small businesses) overcome the hurdles to entering new export markets, by assisting with financing, and in general by working with our international partners, among other steps. In January 2013, the International Trade Administration began previewing New.Export.Gov, which streamlines assistance for exporters. Such measures, along with others to enhance the international trade system, promote investment, trade, and economic growth—all of which promote both the production and the broadest possible exchange of life science-related products and technologies.

8. In addition, the United States promotes exchange in the life sciences in a variety of smaller-scale but more focused ways:

9. The Department of Health and Human Services supports multiple international exchange programmes for scientific research, including the following:

- Food and Drug Administration (FDA)'s International Scientist Exchange Program;
- FDA's Foreign National Training Program;
- National Institute of Health (NIH)'s Visiting Program for scientists, designed to train and conduct collaborative research at NIH;
- NIH/Fogarty International Center, which provides grants to train researchers and build sustainable research capacity in more than 75 low and middle income countries;
- NIH/National Cancer Institute (NCI)'s Short Term Scientist Exchange Program; and

- NIH/National Institute for Allergies and Infectious Disease (NIAID)'s International Centers of Excellence in Research program, which develops research programmes in resource-poor countries through partnerships with local scientists to provide training and improve laboratory and clinical infrastructure.

10. The Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) provided more than $50 million in cooperation with WHO to strengthen the ability of developing countries to sustainably produce influenza vaccines, potentially reducing the global threat of influenza pandemics. In addition, BARDA provided over $20 million to support vaccine adjuvant technology transfer, biomanufacturing workforce training, and clinical trial and manufacturing technical support to developing country influenza vaccine manufacturers. BARDA has also successfully established public-private partnerships with industry partners to develop novel antibiotics, including a five-year, $200 million agreement with GlaxoSmithKline, designed to support the development of an entire portfolio of candidate antibiotic therapies.

11. The Department of State supports biological scientific engagement through a series of vehicles, including:

- Through more than 50 bilateral science and technology agreements, which provide a formal mechanism for United States Government departments and agencies to promote collaboration on scientific endeavors with partner nations; and
- Through endowed science and technology funds used to support patents, publication, and commercial sales.

12. American colleges and universities also engage in joint research collaborations with colleagues across the globe, and educate many of the world's emerging scientists through undergraduate, graduate, and post-graduate training. In 2012, there were more than 284,000 foreign graduate students enrolled in U.S. universities, with more than 163,000 enrolled in science and engineering studies. The number of foreign students enrolled in U.S. undergraduate programmes continues to rise, with an 11% increase between 2011 and 2012 to approximately 351,000. One third of all foreign students enrolled in U.S. undergraduate programmes are enrolled in science and engineering fields.

13. Additionally, many nongovernmental organizations and foundations based in the United States host scientific exchanges and forums to bring together scientists from around the world. Some of these entities explicitly sponsor the scientific development of foreign researchers, including the $200 million Howard Hughes Medical Institute International Early Career Scientist awards program. Another noteworthy example is the Intel international Science and Engineering Fair (ISEF), a program of the Society for Science and the Public. ISEF is the world's largest pre-college science competition. Each year it enables more than 1,700 high school students from about 70 countries, regions, and territories to display their independent research and compete for over $5 million in awards. The American Society for Microbiology also has a robust program to engage international partners, fostering collaboration and partnership, and providing specialized programmes in science communication, evidence-based policy making, microbiology mentorship, lab biosafety and biorisk management.

14. Open access: Many United States institutions support "open access" – the principle of making research results broadly available, free of charge. One of the first book publishers to provide open access was the National Academies Press, publisher for the National Academy of Sciences, Institute of Medicine, and other arms of the National Academies. They have provided free online full-text editions of their books alongside priced, printed editions since 1994. In 1997, the U.S. National Library of Medicine (NLM) made Medline, the most comprehensive index to medical literature on the planet, freely available through PubMed. Since April 2008, the National Institutes of Health has required

that all articles arising from NIH funding be made freely available via PubMed Central within 12 months of publication, and in February 2013, the White House Office of Science and Technology Policy directed all Federal Agencies to develop plans to make published results of federally funded research freely available to the public within one year of publication.

15. In addition, many U.S. colleges and universities have adopted open access policies. Some of these apply only to graduate theses, and others apply to the faculty of specific schools. Some, however, apply broadly to the research of faculty at major U.S. universities. A growing number of major U.S. institutions are also making undergraduate and even some graduate courses freely available online. One of the earliest and most advanced of these initiatives is MIT's OpenCourseWare project, which began in October 2002 and now offers over 2,000 free, online courses. Johns Hopkins Bloomberg School of Public Health also offers dozens of its most popular public health courses online for free.

III. Contributions to the development and application of scientific discoveries in the life sciences for the prevention of disease, and for other peaceful purposes

16. Sometimes overlooked is the undertaking in Article X for Parties "in a position to do so" to contribute to the further development and application of the life sciences. The United States is a world leader in life sciences research and development (R&D), accounting for up to one-third of global investment in life sciences R&D. Much of this work is undertaken by the private sector, although the federal government remains the largest funder of life sciences research at U.S. colleges and universities. This makes the United States one of the foremost engines driving forward both basic science and its application, from universities to government institutes to biotech companies to amateur biologist.

17. Strengthening capabilities to prevent, detect, and treat naturally-occurring diseases is not only one of the most basic and important applications of the life sciences, it is also an important bulwark against the potential misuse of biological agents and toxins; thus, by helping other States Parties strengthen health care infrastructure and build disease surveillance capacity, we are contributing directly to the object and purpose of the BWC, including Article X obligations. To this end, the United States has provided a wide range of assistance to international partners, including, *inter alia*, the following examples designed to reduce threats, improve global detection of disease, enhance capacity to investigate and diagnose biological emergencies, prevent and respond to disease outbreaks, and improve global health.

Threat Reduction

18. The Department of State Biological Engagement Program will provide more than $37 million in fiscal year 2014 funding for programmes focused on laboratory biorisk management, disease detection and control, and cooperative research and development. These programmes were supported in partnership with countries in the Middle East and North Africa, South Asia, Southeast Asia, sub-Saharan Africa, Eurasia, and Latin America. Specific activities included:

- Biorisk assessments followed by biosecurity upgrades in public and animal health laboratories;
- Sustainable biorisk management capacity building through biosafety and biosecurity technical trainings, as well as facilitating a broader awareness of biological nonproliferation issues; and

- Enhancing public and animal disease detection and control capabilities through international scientific and technical exchanges.

19. The Department of Defense is projected to spend a total of over $2 billion through its Cooperative Biological Engagement Program (CBEP) between fiscal year 2012 and fiscal year 2019, and allocated $260 million to this effort in fiscal year 2014 alone. CBEP is focused on reducing the threat posed by pathogens of security concern and related materials and expertise, as well as other emerging infectious disease risks. These programmes were supported in partnership with countries in Eurasia, Southeast Asia, South and Central Asia, the Middle East and sub-Saharan Africa. CBEP provides assistance across the following areas:

- Dismantling, destroying, and preventing the sale, theft, diversion, or use of stockpiles of biological weapons (BW), means of delivery, and BW-related equipment, technology, and infrastructure;
- Enhancing partner country/region's capability to identify, consolidate, and secure collections of pathogens and diseases of security concern
- Enhancing partner country/region's capability to rapidly and accurately survey, detect, diagnose, and report biological terrorism and outbreaks of pathogens and diseases of security concern in accordance with international reporting requirements.

Disease Surveillance and Response

20. In partnership with other nations, international organizations, and public and private stakeholders, the United States launched the Global Health Security Agenda in February 2014, with the intent to prevent and reduce the likelihood of disease outbreaks, detect threats early to save lives, and rapidly respond to outbreaks with a coordinated multisectoral engagement. The United States seeks to accelerate progress toward a world safe and secure from infectious disease threats. The United States is committed to this goal and multiple U.S. Government organizations, including the Centers for Disease Control and Prevention, the Department of Defense, the U.S. Agency for International Development, and the U.S. Department of Agriculture's Agricultural Research Service, have been working to build disease surveillance and response capacity around the world.

21. The Department of Defense's Global Emerging Infections Surveillance and Response System (DOD-GEIS) works to enhance global health security and armed forces health protection through a global network poised to prevent, detect, and respond to emerging microbial threats. The GEIS network and its partners support a wide range of global surveillance efforts across all emerging infectious disease (EID) surveillance through a holistic approach that includes: surveillance activities to prevent, detect and respond to infectious diseases; training and capacity building; research innovation and integration; and coordination, communication and collaboration among GEIS partners to facilitate responsive information sharing. In 2014, GEIS network surveillance and capacity building efforts reached 69 countries. This program effectively communicates information from its surveillance activities to support increased public awareness and understanding of important global issues and shaping of public health decisions. Surveillance findings are routinely shared with the respective Ministries of Defense (MoD) and Ministries of Health (MoH) of the host partner countries. GEIS encourages its partners to present and publish their findings in medical journals, at scientific meetings and to be compliant with the International Health Regulations.

22. In 2014, GEIS distributed $45.7 million to support two different kinds of surveillance activities – ongoing sustainment initiatives and novel proposals. Approximately two-thirds of GEIS sustainment funding supports ongoing initiatives to maintain a robust global EID surveillance portfolio that is standardized across all regions.

The remaining one-third of funding is awarded to projects submitted in response to an annual request for proposals that address novel EIDs or surveillance efforts affecting the Department of Defense and global health communities.

23. The Centers for Disease Control and Prevention (CDC), as the nation's primary agency and worldwide leader for disease detection, has worked in partnership with countries to develop sustainable capacities to support disease surveillance and response activities. CDC's health protection activities include the Global Disease Detection and Response Program (GDD) and the Field Epidemiology Training Program (FETP). Through these programmes, CDC works to prevent, detect, and respond to infectious disease outbreaks and improve global health security by building capacity in the following areas:

- Training in field epidemiology and laboratory methods;
- Surveillance and response for emerging infectious disease threats;
- Assistance with pandemic influenza preparedness;
- Promotion of zoonotic disease investigations and control efforts;
- Risk communications; and
- Laboratory biosafety and improved laboratory systems.

24. In 2013, the total number of people covered by population-based surveillance was 22.8 million. Between 2006 and 2013, GDD detected 58 new pathogens, and deployed 270 pathogen-specific tests to be made available to partner countries. GDD also participated in 1,257 outbreak responses from 2006–2013. In 2013, CDC experts responded to outbreaks for diseases including meningitis, MERS CoV, Dengue, Nodding Syndrome, Monkeypox, novel influenza, and Chikungunya.

25. The U.S. Agency for International Development's (USAID) Emerging Pandemic Threats (EPT) program seeks to aggressively pre-empt or combat diseases that could spark future pandemics, emphasizing early identification of and response to dangerous pathogens in animals before they can become significant threats to human health. The EPT program draws on expertise from across the animal and human health sectors to build capacities for early disease detection, laboratory-based disease diagnosis, rapid disease response and containment, and risk reduction. Partners include organizations with specialized expertise in wildlife monitoring, field epidemiology and training, laboratory strengthening, and behavior change communications, as well as international partners from the World Health Organization (WHO), the United Nations Food and Agriculture Organization (FAO), and the World Organization for Animal Health (OIE). The first iteration of the EPT Program is coming to a close in September 2014. USAID is in the process of developing the second iteration, EPT-2, which will launch in October 2014.

26. The Department of Agriculture's Agricultural Research Service (ARS) is actively engaged in implementing research programmes that help prevent, detect, or improve surveillance of plant and animal disease, including emerging disease and zoonotic agents that pose a threat to human health. ARS also actively collaborates with international partners worldwide on research projects dedicated to support disease surveillance programmes for transboundary animal diseases such as animal influenza viruses with epizootic and/or pandemic potential, Foot-and-Mouth Disease (FMD), and African Swine Fever (ASF). ARS is one of the founding members of the Global Foot-and-Mouth Research Alliance (GFRA), the African Swine Fever Research Alliance (GARA), and is an active member of the global network of expertise on animal influenza (OFFLU), which supports the FAO and OIE global efforts to control and eradicate transboundary animal diseases that impact the health of animals and people worldwide. ARS also partners with the American

Biosafety Association (ABSA) to conduct biosafety training relevant to agriculture to many national and international participants at a biennial symposium.

Enhancing Capacity

27. The United States supports the WHO's International Health Regulations (2005), which, *inter alia*:

- Provide a framework for WHO alert and response activities that are implemented in collaboration with countries to control international outbreaks and other public health risks and emergencies;
- Allow the WHO to provide support for the implementation of national capacities for epidemic preparedness and response, including laboratory capacities and early warning alert and response systems; and
- Standardize approaches for readiness and response during a public health emergency of international concern, allowing the International Health Regulations Emergency Committee to issue travel and trade recommendations based on the best evidence available.

28. The U.S.A. CDC established the Field Epidemiology (and Laboratory) Training Programmes (FELTP) in 1980, and since then CDC has helped launch more than 50 programmes around the world and produced more than 3,000 graduates. CDC currently supports workforce development through FELTPs in 46 countries, which are designed to build human capacity to characterize disease burden, respond to outbreaks, provide diagnostic capacity, and address locally-identified public heath challenges. From 2009-2012, CDC-supported FELTP residents responded to over 1100 outbreaks and conducted 606 planned studies and 1268 surveillance assessments. Through these activities, FELTP residents and graduates strengthen critical public health systems, improve the effectiveness of key public health programmes, and address their countries' public health priorities.

29. The U.S. Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services engages with international partners to create an all-hazards approach to improve our collective capabilities to deal with public health emergencies including those that arise from chemical, biological, radiological and nuclear (CBRN) threats, outbreaks of emerging infectious diseases, and natural disasters. Accordingly, the ASPR leads international programmes, initiatives and policies to strengthen domestic and international public health and medical emergency preparedness and response, including coordinating efforts to rapidly exchange information and biological materials during acute public health emergencies.

Improve Global Health

30. The U.S. Government is the leading funder of global health assistance; in FY12, the US government spent approximately $ 8.8 billion (estimated) in the Global Health Initiative alone, with an estimated $1-2 billion in additional global-health related funding in other initiatives and mechanisms. The United States is a major contributor to the Global Fund for AIDS, Tuberculosis, and Malaria, the WHO, and the Global Access to Vaccines Initiative Alliance. The U.S. Government's financial and technical contributions significantly improve and expand sustainable health systems and support the goal of a world safe and secure from emerging infectious disease threats. In 2014, the US government further pledged to work in partnership with at least thirty other countries, encompassing four billion people worldwide, in the next five years, to improve the prevention, detection and response to infectious disease threats.

IV. Efforts to avoid hampering economic or technological development, or international cooperation in the life sciences, including agents and equipment related to biological agents, for peaceful purposes

31. An effective system of national export controls continues to be essential to enhance the avenues of free trade necessary for the implementation of Article X. The U.S. Government's export licensing system is designed to be fast, transparent, and effective in fulfilling our Article III and United Nations Security Council Resolution 1540 obligations and guarding against the risks of proliferation and terrorism. The Department of Commerce's Bureau of Industry and Security (BIS) implements the U.S. Government's export control system for dual-use items, those items that have chiefly commercial uses but that also can be used in conventional arms or weapons of mass destruction (WMD) applications, terrorist activities, or human rights abuses. In August 2010, President Obama announced the foundation of a new export control system designed to strengthen U.S. national security and increase the competitiveness of key U.S. manufacturing and technology sectors by reforming our existing system and adapting it to the changing economic and technological landscape. When completed, this export control reform initiative will result in a single control list, a single licensing agency, a single primary enforcement coordination agency, and a single information technology system.

32. To accomplish its objectives, BIS administers, and amends as necessary, the U.S. Export Administration Regulations. BIS issued licenses for only $8 billion in exported goods in 2013, of the nearly $1.6 trillion in goods exports from the United States in 2013- only 0.005%. Therefore, consistent with our obligations under Article X of the BWC, these regulations have a minimal impact on overall trade.

33. The Department of State's Export Control and Related Border Security (EXBS) Program seeks to prevent the proliferation of weapons of mass destruction (WMD) and irresponsible transfers of conventional weapons by helping to build effective national strategic trade control and border security systems.

34. To achieve this goal, the EXBS Program helps strengthen partner countries' legal authorities and institutional capabilities:

- To regulate trade in sensitive items and prevent transfer authorizations that may contribute to proliferation;
- To target high-risk shipments, detect and interdict illicit trafficking at and between ports of entry, and prosecute violators; and
- To build and sustain a community of policymakers and technical experts committed to implementing effective strategic trade controls.

35. By strengthening authorities and institutional capacities in these critical areas, the EXBS Program helps key partners conform to international standards for regulating trade in items on the control lists of the multilateral export control regimes and meet their obligations pursuant to important international initiatives, including United Nations Security Council Resolution 1540.

36. The EXBS Program engages more than 65 partners worldwide. With 22 in-country advisors and 45 locally hired staff, the EXBS Program supports these partners by implementing more than 250 capacity building and outreach activities each year. Within the United States Government, the EXBS Program coordinates closely with the Department of Defense's International Counter-Proliferation Program; the Department of Energy's International Nonproliferation Export Control Program and Second Line of Defense

Program; and the State Department's Antiterrorism Assistance Program and the Bureau of International Narcotics and Law Enforcement's assistance programmes.

37. Finally, the NIH Office of Biotechnology Activities works to raise awareness of the implications of dual-use research among governments and government entities, the life science research community, and the scientific publishing community. Within the U.S. Government, agencies that have a vested interest in life sciences research coordinate closely in developing approaches that will stimulate such research, while at the same time assuring that potential concerns are assessed and evaluated. The National Science Advisory Board for Biosecurity (NSABB) is a federal advisory committee chartered to provide advice, guidance, and leadership regarding biosecurity oversight of dual-use research; a selection of NIH documents and NSABB recommendations can also be found in the Appendix attached at the end of this report.

V. Case Study: Responding to a Request for Assistance Through the ISU Assistance and Cooperation Database

38. The Implementation Support Unit (ISU) collates and publishes formal requests for and offers of assistance by BWC Parties; in 2012 and 2013, the Government of Iraq requested support through the ISU for a number of activities related to BWC implementation, including biosafety and biosecurity, bioethics, biorisk management policies, bioterrorism risk reduction, and biorisk assessments. The United States Government (USG) responded to this request and has engaged with Iraq to further define its needs and provide assistance focused on supporting the development of self-sustaining facilities and practices. This section summarizes USG assistance in these areas, and primarily covers activities supported by the Department of State's Biosecurity Engagement Program (BEP) and the Department of Defense's Cooperative Biological Engagement Program (CBEP).

Biosafety and Biosecurity (including biosecurity culture)

39. The USG provided assistance to Iraq on biosafety and biosecurity via rapid physical security upgrades and the provision of biorisk management training to life scientists. In 2011, USG engagements provided rapid physical security upgrades to selected government diagnostic laboratories in Baghdad. Scientists from these facilities have also been trained in biorisk management best practices, including secure and safe infectious substance shipping. In 2014, the USG supported a Trainer Development Program, which taught Iraqi laboratorians and researchers how to train others on biorisk management in order to build a self-sustaining system. In providing this support, the USG strives to provide Iraqi partners with international best practice guidelines and standards. Additional biorisk management activities, such as training, workshops and a table-top exercise for government laboratories, are planned for the coming year.

Bioethics

40. The importance of responsible research conduct and a strong awareness of bioethical issues have been highlighted as key issues in biological threat reduction in recent years. In 2013, the USG supported a workshop on bioethics for university professors and students from a number of Iraqi universities. More recently, in 2014, the U.S. National Academy of Sciences invited three Iraqi professors, from universities in Baghdad and Babylon, to participate in one of their internationally-recognized dual-use "Institutes". The objectives of the Institute is for participants to not only learn about dual-use issues, but also gain experience with methods for teaching these topics, have the opportunity to develop their own teaching materials, and learn how to integrate issues of responsible conduct and

bioethics into the existing curricula at their institutions. The Institute was very successful, and a follow-on Institute is planned for 2015 involving additional groups of Iraqi researchers and professors.

Biorisk management policies (including pathogen classification into risk groups)

41. The United States Government (USG)'s most important partner organization in Iraq with respect to biorisk management policy is the Iraq National Biorisk Management Committee (NBMC). The NBMC is comprised of representatives from 15 Iraqi ministries with equities related to biorisk management and is mandated to develop and implement policies to reduce the risk of biological threats. The USG supported the NBMC's first international meeting in Amman, Jordan, in 2013, and later in the year supported a follow-on meeting in Baghdad, which included external consultants at the NBMC's request. During these meetings, the NBMC identified two objectives for immediate priority: development of a national biorisk management policy, which could be further developed into legislation assisting Iraq in demonstrating compliance with the BWC and other international nonproliferation treaties; and the creation of a pathogen control list (based on risk groups) which could be used for import/export control as well as regulation of research on especially dangerous pathogens. At a recent international meeting supported by the USG, with technical support provided by international experts such as VERTIC, the NBMC made significant progress towards meeting these two objectives, and the Committee continues to work closely with the USG as they finalize the draft policy and pathogen list.

Bioterrorism risk reduction

42. Given the threats emanating from conflicts in the region, the USG has responded to Iraqi requests for assistance specifically related to terrorism threats from unconventional weapons, including biological weapons. From a response standpoint, the USG has been working closely with the Iraqi government to develop a national chemical, biological, radiological, and nuclear response plan to include a national biological emergency response plan. These efforts also involve partnership on development of an Emergency Operations Center in the Ministry of Health, to better coordinate response by public health first responders in the event of a biological attack or other biological incident. From a prevention standpoint, in 2013–2014, the USG partnered with several Iraqi ministries and agencies to provide training on chemical detection, investigation, and forensics training, and there are plans to expand these trainings to include biological incident detection and investigation in the coming year.

Biorisk assessment

43. Prior to conducting physical security upgrades at select facilities in Baghdad, experts conducted risk assessments to determine the biosecurity needs and priorities at each facility. In addition, experts have conducted risk assessments at other facilities within Iraq, including several government laboratories in the northern region. Given the access challenges to many parts of the country, the USG has been working with Iraqi partners to explore other methods for conducting risk assessments for laboratories and institutions outside of Baghdad and Erbil. In 2013, the USG awarded a multi-year Biological Threat Reduction Integrating Contract (BTRIC) for work in Iraq. The BTRIC will develop a biosecurity and biosafety baseline which includes identifying current capacities and capabilities to achieving biological security in Iraq; conducting laboratory biosafety and biosecurity assessments; performing rapid security upgrades at provincial laboratories; conducting technical capabilities assessments of laboratory and field staff; building capacity for sample transport; and delivering in-country training to select laboratories. The contractor will coordinate, integrate and implement projects and activities in Iraq in order to enhance biosafety and biosecurity standards and procedures. In 2014–2015, the USG has

plans to initiate a comprehensive risk assessment training program in Iraq, including developing a cadre of Iraqi risk assessment trainers who will continue the implementation of training throughout the country.

V. Conclusion

44. International cooperation and exchange in the life sciences and in combating disease will continue to be a core objective for the United States and is consistent with our obligations under Article X of the Biological Weapons Convention. International cooperation to support the advancement of biological sciences for peaceful purposes; assistance to improve global health through the prevention, detection, and mitigation of disease; and the development of capacity and collaborative opportunities for scientists across the globe are all areas in which the United States will continue to commit programmes and resources. Furtherance of these aims has broad support in all sectors of the United States, including the U.S. Government, non-governmental institutions, industry, the scientific community, civil society, and the American people.

Annex

Training Programmes

Building on the programmes identified in the previous sections of this paper, below are some of the many federal or federally-funded training programmes that conduct work with foreign scientists, including many that are free and open to all. This list is not exhaustive and thus does not include the many additional resources available that have been developed by industry, foundations, academia, or other non-governmental entities.

Online training and educational materials

Emergency Preparedness and Response

The CDC provides resources that are intended to help professionals take an all-hazards approach to preparedness. These materials are available online at: http://emergency.cdc.gov/hazards-all.asp. A list of training resources related specifically to bioterrorism is available online at: http://emergency.cdc.gov/bioterrorism/training.asp.

The Public Health Training Centers Network

This is a distance learning network of people and resources that takes training and information to the learner. A listing of distance learning courses and resources is available online at: http://bhpr.hrsa.gov/grants/publichealth/trainingcenters/index.html

Training and Continuing Education Online (TCEO)

TCEO is a distance learning network that allows participants to register for CDC-managed courses and track their progress online. TCEO is available online at: http://www2a.cdc.gov/TCEOnline/index.asp.

Other learning resources are available online at the CDC Learning Connection Website (http://www.cdc.gov/learning/index.html)

This is a newly established website, designed to help visitors locate public health learning products created by CDC and partners. It features a growing collection of free products in various media formats, including podcasts, e-learning, electronic publications, and live events.

In-person training programmes

The National Biosafety and Biocontainment Training Program (NBBTP)

http://www.nbbtp.org

Emory University - Biosafety Training Course: Biosafety Level 4

This five-day training offers participants the opportunity to learn and practice new skills for BSL4 labs. http://www.sph.emory.edu/CPHPR/biosafetytraining/bsl4.html

University of Texas Medical Branch (UTMB) - National Biocontainment Training Center (NBTC)

This center is dedicated to preparing the worldwide community of infectious disease scientists to work safely in high-containment research laboratories. http://www.utmb.edu/nbtc/

Select Agent Program Training Workshops

The U.S Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) conduct training workshops to inform individuals of their legal responsibilities for implementing the Select Agent Regulations. The website hosts a collection of past presentations and training webcasts. http://www.selectagents.gov/Training.html

Joint Criminal and Epidemiological Investigation Training Program

The Federal Bureau of Investigation (FBI) and the Centers for Disease Control and Prevention (CDC) jointly developed this program to improve efforts to identify and investigate potential overt or covert biological threats. Initially designed as a domestic program, FBI and CDC have expanded this training to international partner countries.

The Field Epidemiology Training Program (FETP) and the Field Epidemiology and Laboratory Training Program (FELTP)

CDC offers applied epidemiology programmes to help foreign countries develop, set up, and implement dynamic public health strategies to improve and strengthen their public health system and infrastructure. The FE(L)TP programmes include biosafety and bioethics training in support of epidemiological activities. http://www.cdc.gov/globalhealth/fetp/

FBI Synthetic Biology Program

FBI conducts outreach to public and private synthetic biology companies to raise awareness about the potential security risks inherent to the industry, and works with the companies to develop common standards and best practices for risk management. The international component of this program fosters dialogue between international companies and their respective government/law enforcement agencies to develop processes to mitigate the risk of misuse of harmful DNA sequences. They also host academic biosecurity training workshops to promote biosecurity practice.

Additional online resources

The CDC Learning Connection

This site maintains a compendium of free learning products on a wide variety of health issues, including Emergency Management, Infectious Disease, Legal/Ethical Issues, Policy/Planning, Preparedness and Response, and Public Health. http://www.cdc.gov/Features/CDCLearning/

The CDC Online Training Course

This course provides education regarding key principles for securing biological agents in research laboratories and biomedical facilities where loss, theft, release or intentional misuse of the agent might have significant public health or economic consequences.

http://www.cdc.gov/biosafety/biosecuritytraining/page1024.html

The FDA's Food Defense and Emergency Response-Training

The U.S. Food and Drug Administration (FDA) works with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply. Web-based training and additional educational resources are available at: http://www.fda.gov/Food/FoodDefense/default.htm

Facility Inspection videos (BSL-3/toxins laboratories)

These informational videos are for entities or individuals who currently possess, store, or transfer select agents and toxins and those who are planning to begin work with select agents or toxins. http://www.selectagents.gov/FIV.html

Global Biorisk Management Curriculum Development (GBRMC)

CBEP has developed and is implementing a biorisk management curriculum to address biosafety and biosecurity training. Users of the training materials can participate in a virtual network of trainers via a web-based portal, and provide lessons learned, updates, and feedback for the continual improvement of the materials. The network of trainers currently consists of more than 100 biosafety professionals active in the United States, Europe, Asia, and Africa.

The Executive Office of the President, Office of Science and Technology Policy website

This site provides information to the public, academic and private sector research communities about government policies related to the safe and secure conduct of biological research and the technologies arising out of the application of the life sciences. http://www.whitehouse.gov/administration/eop/ostp/nstc/biosecurity

The S3 (Science, Safety, and Security) website

This website provides information on biosafety, biosecurity, biocontainment, and biorisk management. http://www.phe.gov/s3/Pages/default.aspx

NIH Dual-Use Research video

http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-of-concern/dialogue

NIH-Dual-Use Education al Materials

http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern

NSABB Oversight Framework Report: Proposed Framework for the Oversight of Dual Use Life Sciences Research

Strategies for Minimizing the Potential Misuse of Research Information:

http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb

Biological Risk Management and Nonproliferation website

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), established this website to increase awareness of the BWC and UN Security Council Resolution 1540. http://www.phe.gov/about/OPP/Pages/bwc.aspx

The Department of Commerce, Chemical and Biological Controls Division

The Chemical and Biological Controls Division (CBC) is the focal point within the United States Government (USG) for implementing dual-use export controls for biological (CB) equipment, materials and technology (e.g., toxins, pathogens, fermenters). These export controls are in place biological weapons concerns and to prevent the diversion of such items to destinations and end-users of concern. http://www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemical-and-biological-controls